

# Notice of Allowability

Application No.

10/815,388

Examiner

Allison M. Ford

Applicant(s)

CAVIEDES ET AL.

Art Unit

1651

## -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to telephonic interview of 29 August 2007.
2. ☒ The allowed claim(s) is/are 18,21-23,25,26,30,31 and 33-61.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### DETAILED ACTION

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Glenn Ladwig on 29 August 2007.

Please use the following version of the claims:

1-17 (Cancelled)

18. A cell culture comprising:

process-forming neurons or glial cells of the central nervous system;  
a cell culture medium; and  
a solid substrate supporting said cell culture medium;  
wherein said neurons or glial cells lack processes, are clustered into one or more aggregates suspended in said cell culture medium, and are not attached to said substrate; and  
wherein said cell culture medium has a calcium concentration of 100  $\mu\text{M}$  or less.

19-20. (Cancelled)

21. The cell culture of claim 18, wherein said solid substrate comprises polystyrene and has an untreated surface for supporting said cell culture medium.

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22. The cell culture of claim 21, wherein said solid substrate is a culture vessel selected from the group consisting of a Petri dish, flask, bottle, plate, tube, and vial.

23. The cell culture of claim 18, wherein said solid substrate comprises untreated plastic.

24. (cancelled)

25. The cell culture of claim 18, wherein said solid substrate has a surface supporting said cell culture medium, and wherein said surface lacks charged molecules.

26. The cell culture of claim 18, wherein said cell culture medium has a calcium concentration of 50  $\mu$ M or less.

27-29 (Cancelled)

30. The cell culture of claim 18, further comprising process-forming cells other than said neurons or glial cells of the central nervous system.

31. The cell culture of claim 18, further comprising non-process-forming cells.

32. (Cancelled)

33. The cell culture of claim 18, wherein said cell culture medium lacks calcium ion as a formulated component.

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34. The cell culture of claim 18, wherein each of said one or more aggregates has an average diameter in the range of 150  $\mu\text{m}$  to 200  $\mu\text{m}$ .

35. The cell culture of claim 18, wherein said neurons or glial cells within each of said one or more aggregates includes living cells that remain viable *in vivo* upon implantation.

36. The cell culture of claim 18, wherein said neurons or glial cells are fully differentiated.

37. The cell culture of claim 18, wherein said neurons or glial cells are brain cells.

38. The cell culture of claim 18, wherein said neurons or glial cells are human cells.

39. A cell culture comprising:

- process-forming neurons or glial cells of the central nervous system;
- a cell culture medium; and
- an untreated, polystyrene microbiological plate;

wherein said neurons or glial cells lack processes, are supported by said plate, are clustered into one or more aggregates, and are not attached to said plate; and

wherein said cell culture medium has a calcium concentration of 100  $\mu\text{M}$  or less.

40. A method for producing the cell culture of claim 18, comprising:

- placing the neurons or glial cells in the cell culture medium; and

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culturing the neurons or glial cells for a period of time sufficient for the neurons or glial cells to cluster into one or more aggregates,

thereby producing a cell culture comprising process-forming neurons or glial cells of the central nervous system, wherein the neurons or glial cells lack cell processes, are clustered into one or more aggregates, and wherein the cell culture medium has a calcium concentration of 100 uM or less.

41. A method for producing the cell culture of claim 39, comprising:

placing the neurons or glial cells in the cell culture medium; and

culturing the neurons or glial cells for a period of time sufficient for the neurons or glial cells to cluster into one or more aggregates,

thereby producing a cell culture comprising process-forming neurons or glial cells of the central nervous system, wherein the neurons or glial cells lack cell processes, are clustered into one or more aggregates, and wherein the cell culture medium has a calcium concentration of 100 uM or less.

42. A method for preparing process-forming neurons or glial cells for transplantation, comprising:

providing said cell culture of claim 18;

removing said one or more aggregates from said culture; and

combining said one or more aggregates with a pharmaceutically acceptable carrier.

43. A method for preparing process-forming neurons or glial cells for transplantation, comprising:

providing said cell culture of claim 39;

removing said one or more aggregates from said culture; and

combining said one or more aggregates with a pharmaceutically acceptable carrier.

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44. The cell culture of claim 18, wherein said neurons or glial cells are primary cells.
45. The cell culture of claim 18, wherein said neurons or glial cells are cells of a cell line.
46. The cell culture of claim 39, wherein said neurons or glial cells are primary cells.
47. The cell culture of claim 39, wherein said neurons or glial cells are cells of a cell line.
48. The cell culture of claim 18, wherein said neurons are dopaminergic cells.
49. The cell culture of claim 39, wherein said neurons are dopaminergic cells.
50. The cell culture of claim 18, wherein the process-forming neurons or glial cells are neurons.
51. The cell culture of claim 18, wherein the process-forming neurons or glial cells are glial cells.
52. The cell culture of claim 39, wherein the process-forming neurons or glial cells are neurons.
53. The cell culture of claim 39, wherein the process-forming neurons or glial cells are glial cells.
54. The method of claim 40, wherein the process-forming neurons or glial cells are neurons.
55. The method of claim 40, wherein the process-forming neurons or glial cells are glial cells.

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56. The method of claim 41, wherein the process-forming neurons or glial cells are neurons.

57. The method of claim 41, wherein the process-forming neurons or glial cells are glial cells.

58. The method of claim 42, wherein the process-forming neurons or glial cells are neurons.

59. The method of claim 42, wherein the process-forming neurons or glial cells are glial cells.

60. The cell culture of claim 43, wherein the process-forming neurons or glial cells are neurons.

61. The method of claim 43, wherein the process-forming neurons or glial cells are glial cells.

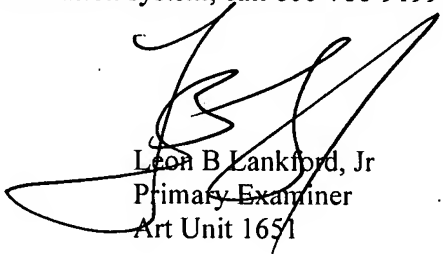
### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Primary Examiner  
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